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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/468,471	12/21/1999	VINCENT DIVINO, JR.	THOX:0021--1	3676

27405 7590 10/23/2002

THEROX, INC.
2400 MICHELSON DRIVE
IRVINE, CA 92612

EXAMINER

BIANCO, PATRICIA

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 10/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/468,471

Applicant(s)

DIVINO, JR. ET AL.

Examiner

Patricia M Bianco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 41-78 is/are pending in the application.
- 4a) Of the above claim(s) 56-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 41-55 and 68-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 & 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Office Action*.

Patricia M Bianco
10/19/02

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1 and 41-55, in Paper No. 11 is acknowledged. The traversal is on the ground(s) that Groups I-III are not distinct and that the search and examination of all the claims would not be unduly burdensome to the examiner. This is not found completely persuasive.

The arguments presented with respect to Group III being the same invention of Group I are persuasive. Therefore, claims 68-78 have been examined with the claims of the elected invention of Group I.

However, applicant's arguments with respect to Group II being directed to the same invention of Groups I & III are not persuasive. First, the invention of Groups I & III are substantially different from the invention of Group II since I & III do not require the pump and gas-supersaturated fluid supply assembly as required by Group II. Applicant also argues that the examination of all the claims not being burdensome. In the restriction requirement the examiner did not rely upon such an argument. The inventions require different structures and therefore the inventions are different as shown by their different classification in the art.

Claims 56-67 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

Response to Preliminary Amendment

The amendment to the title has been entered, the continuity information added to the specification, and claims 2-40 cancelled as filed in the preliminary amendment.

Drawings

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

✓ The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "mixing device," "mixer," "mixing chamber," the "first inlet," the "second inlet," and their arrangement with the "mixing chamber" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

✓ The abstract of the disclosure is objected to because of length. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed

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150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. Correction is required. See MPEP § 608.01(b).

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the claimed "mixing device," "mixer," "mixing chamber," the "first inlet," the "second inlet," and their arrangement with the "mixing chamber" have no support in the specification as filed. The specification refers to a *chamber* for formulating the super-saturated solution. However, it is not clear if the disclosed *chamber* and the claimed "mixing device" are one and the same. If they are describing the same structural feature of the invention, it is suggested that applicant choose either chamber or mixing device and amend the specification and/or claims to reflect the specific structure of the invention to be consistent.

The use of the trademarks has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. It appears that numerous trademarks have been recited without proper indication (such as ® or ™) after each. Clarification and proper indication of trademarks is required for the following: **AKZO OXYPHAN™**

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

✓ Claim 51 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how the mixer is "being arrange to create a vortical flow" within the chamber.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

now parent case
w/d Claims 1, 41-45, 47-50, 52-54, 68 and 70-72 are rejected under 35 U.S.C. 102(e)

as being anticipated by Divino, Jr. (6,180,059). Divino, Jr. et al. (hereafter Divino) discloses a system and method of using said system for enriching blood by supplying an oxygen-supersaturated fluid to the blood intravascularly. A catheter 40 comprises a housing 42, a first tubular member 48 defining a lumen 52 between a proximal and distal end that is adapted to receive a supply of blood via an inlet lumen 44. The tubing

used is capable of providing continuous fluid flow to the chamber. Lacking any definitive structure disclosed in the specification, the catheter is seen to be equivalent to the "mixing device" and its lumen equivalent to the "mixing chamber." The distal end of the first member is inserted into the vasculature of a patient. A second tubular member 54 is adapted to be coupled to a supply of oxygen-supersaturated fluid 32 that is located extravascularly to the catheter (see figure 1). With respect to claims 53 and 54, the two inlets (44, 52) are arranged in an way that the fluids delivered to the respective lumens are substantially perpendicular or substantially opposite each other. The oxygen-supersaturated solution exits the distal end 58 of the second tubular member, via port 56, in an area within the lumen of the first tubular member. Such combination of the oxygen-supersaturated solution and blood in this area avoids the formation of significant amounts of gas bubbles. Divino shows blood supplied from the patient to the catheter (i.e. "mixing device") mixed with a supersaturated solution. After the blood is supersaturated it is returned to the patient. The second tubular member may be a single tubular member or be comprised of one or multiple capillary tube members. With respect to claims 48, 49, 50, and 70-72, Divino teaches that the blood may be hyperoxic (greater than 400 mmHg but less than 760 mmHg) or hyperbaric (greater than 760 mmHg) after being enriched with the supersaturated solution. With respect to claims 42-45, the supersaturated fluid used is oxygen gas which inherently has a gas and a liquid phase and oxygen is well known to be isotonic to blood. (See entire disclosure including the figures)

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Claims¹, 41-45, 47, 48, 50, 53-55 and 68-75 are rejected under 35 U.S.C. 102(b) as being anticipated by Grady (5,084,011). Grady teaches of a system and method for oxygenating blood extracorporeally. The system includes a vessel, having a chamber for holding the fluids, for mixing a gas and a fluid under pressure. Lacking any definitive structure disclosed in the specification, the vessel is seen to be equivalent to the "mixing device" and its interior equivalent to the "mixing chamber." After the supersaturated solution has been made, the vessel may be connected to either intravenous tubing or a syringe pump to infuse said solution with blood in the vasculature of the patient. With respect to claims 53 and 54, the two inlets (22,48) are arranged in an way that the fluids delivered to the respective lumens are substantially perpendicular or substantially opposite each other. With respect to claims 73 and 74, Grady teaches that the chamber may be maintained at about 4 atm pressure (i.e. 3040 mmHg) and therefore the claim limitations are met. With respect to claims 42-45, the supersaturated fluid used is oxygen gas which inherently has a gas and a liquid phase and oxygen is well known to be isotonic to blood. With respect to claims 48, 50, and 70-72, Grady teaches that the blood may be hyperbaric (greater than 760 mmHg) after being enriched with the supersaturated solution. (See entire disclosure including the figures)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

⁴⁶
Claims 5 & 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Divino, Jr. (6,180,059) in view of Spears (5,693,017).

Divino substantially discloses the invention as claimed, see explanation above, except for using saline as the fluid that is supersaturated in the supersaturated fluid supply of the system and wherein the fluid is supersaturated under pressure within the mixing device.

Spears teaches of using saline as the fluid to be saturated with a gas in an apparatus and method for delivering supersaturated solutions to a delivery site. The supersaturated fluid supply is made in a vessel that is under pressure. The dissolving of oxygen or other gas under pressure ensures that no bubbles are in the fluid prior to delivery to the patient.

It would have been obvious to one having ordinary skill in the art to modify the system of Divino such that saline is used as the fluid to be supersaturated with oxygen


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and that the saturation is done under pressure. The use of saline is well known in the art since saline is isotonic with blood. Dissolving a gas under pressure ensures that no bubbles are in the fluid prior to delivery to the patient to ensure that no embolism are formed.

Conclusion

Any inquiry concerning the rejections contained within this communication or earlier communications from the examiner should be directed to Tricia Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday through Fridays from 9:00 AM until 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned is (703) 306-4520 for regular communications and for After Final communications.

pmb 
October 19th, 2002